PROSTATE CANCER SCREENING: AVOIDING LIABILITY

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Carcinoma of the prostate (CaP) is the most common solid malignancy in men. It is estimated that in 1996, there will be 317,000 new cases diagnosed, a thirty percent increase from the cases discovered in 1995. In addition, there will be an estimated 41,400 deaths from the disease in the United States.[1] The increase in newly diagnosed CaP is secondary to the relatively new diagnostic modalities of transrectal ultrasonography (TRUS) and the use of the prostate specific antigen (PSA). With the ability to diagnose CaP enhanced by these two diagnostic modalities, especially PSA, the issue of appropriate screening is raised.

The American Cancer Society and the American Urological Association have recommended annual prostate cancer screening with digital rectal examination (DRE) and prostate specific antigen (PSA) testing for men starting at age 50. For African-American men, and men with a family history of a first-degree relative with prostate cancer, it is recommended that screening consisting of a DRE and PSA start at age 40.[2] No age is specified for stopping the test, although a ten-year life expectancy of the person in question is sometimes cited as an end point.

Several factors favor the use of screening for the early detection of prostate cancer.[3] First, because patients do not experience symptoms during the early stages, they are unlikely to seek care until the disease has progressed. Second, improvements in detection methods have increased the prospects of identifying the disease in its early stages, when the cancer is still confined to the organ and is potentially curable. Third, early detection might mean the difference between life and death, as no cure has been found for advanced disease. In addition, the aging population results in an increased risk to men for developing CaP.

In a summary of available evidence on effectiveness and cost of prostate cancer screening in elderly men, the Congressional Office of Technology Assessment (OTA) concluded that research to date has not determined whether screening extends lives. Yet, despite scientific uncertainty, the OTA concluded that it may be reasonable for Medicare to consider reimbursement of screening. OTA reported that both PSA blood testing and DRE in a physician's office are feasible tests.[4] The OTA suggested that, as an alternative to establishing permanent Medicare reimbursement of prostate cancer screening, such screening would be offered on a temporary basis while clinical trials continued on discerning the best methods.

Believing that prostate cancer screening leads to early detection, which in turn can both reduce future health care costs and reduce deaths, the Minnesota legislature passed a bill that requires insurers in the state to cover prostate cancer screening for all men over fifty.[5] In line with the recommendations by the American Cancer Society, they must also cover men over forty who are symptomatic or who are in a high risk category. At a minimum, the screening must consist of a PSA blood test and a DRE.

Despite these recommendations for prostate cancer screening by professional medical associations and the acceptance of such recommendations in the political arena, support for PSA screening is not universal. In its latest report, the U.S. Preventive Services Task Force recommended against routine

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screening with DRE, serum tumor markers (e.g., PSA), or transrectal ultrasonography (TRUS).[6] The report was based on a five year review of scientific evidence on the effectiveness of preventive measures. In addition to the Task Force, the American College of Physicians and the National Cancer Institute have also argued against screening.

Opponents of screening point to the potential for adverse side effects from radiation therapy, surgery or cryotherapy, the possibility that some men will be treated unnecessarily, the economic burden of screening on the health care system, and finally, the lack of scientific evidence that screening will reduce disease-specific mortality.[7] In elderly patients with well differentiated tumors, for example, watchful waiting may be preferable. Medical groups have also voiced concern that the use of PSA as a routine screening test would establish a legal standard of care that would place an undue burden on physicians, subjecting them to increased malpractice actions.

MEDICAL MALPRACTICE

The law of negligence that governs medical malpractice cases can be seen in terms of four fundamental elements: duty, breach, causation and damages. Once a physician undertakes the care of a patient, the physician acquires a legal duty to provide care that conforms to accepted standards of medical practice. Negligence is a breach of this duty resulting in harm to the patient.

The standard of care for a physician demands that his or her conduct measures up to the standard of care and skill ordinarily possessed by others in the profession. If a physician practices as a specialist, the physician is held to the standard of care and skill of the average member of the profession practicing that specialty.

In a medical malpractice case, usually a physician, as a professional peer of the defendant, provides the required evidence at trial regarding the professional standard of care governing the defendant physician's duty and whether that standard was breached. The expert witness testifies as to what is customary practice based on his or her general knowledge, supported by textbooks, medical journals, or a professional organization's guidelines or recommendations.

When professional organizations' recommendations or guidelines conflict, as in the case of prostate cancer screening, can such guidelines be introduced as evidence of professional standards? If introduced, what effect can conflicting guidelines or recommendations have? An example is seen in the following case.

After a 74-year-old woman died of breast cancer, her husband brought suit against her doctor for failing to recommend or to order a screening mammogram for the patient during the three years prior to the diagnosis of her breast cancer.[8] Medical experts for both sides based their testimony regarding whether the standard of care was breached on guidelines established by professional medical associations. Because the guidelines conflicted and experts disagreed as to the impact of the various guidelines, the trial court excluded them as evidence of professional standards. The appellate court determined that the guidelines, although contested, should be admitted as evidence of professional standards. The jury would have to hear all the arguments and determine the weight to be granted the evidence, and the jury would then establish the applicable standard of care in this case. This case would argue, then, that while clinical guidelines are not always controlling, they can be significant and persuasive.

A HYPOTHETICAL

A 50-year-old bank president, in good general health, visited a local urologist for an initial routine examination and explained that prostate cancer had been diagnosed in both his father and his grandfather. His grandfather died in his late seventies of an unknown cause, and his father died in his mid-seventies of heart disease. The patient had no urologic complaints and the DRE was normal. The patient specifically inquired about the appropriateness of screening with a PSA. The urologist discouraged PSA testing, explaining that scientific evidence did not exist to clearly support early detection of prostate cancer through PSA testing. The blood test was not performed.

The patient returned the following year for an annual urological examination. Once again, he had no urologic complaints, and findings on DRE were normal. He again requested PSA screening, heeding recommendations outlined in the health column of his local paper. Blood work was drawn and the patient's PSA level was elevated at 19.1 ng/mL (normal $\leq$ 4.0 ng/mL).

The patient immediately underwent a prostate biopsy which revealed moderately differentiated prostate cancer. A radical prostatectomy was scheduled; however, it was found at the time of surgery that the patient had pelvic node metastases. In spite of radiation therapy, one year after the initial diagnosis, multiple metastases were revealed on a bone scan.

Is the patient in this hypothetical justified in filing a malpractice action, claiming that the urologist was negligent in failing to order a PSA test at the initial consultation? The American Urological Association and American Cancer Society recommendations would support such a claim. The patient, a 50-year-old man with a family history of a first-degree relative with prostate cancer, fell well within the parameters for screening.

The urologist's decision to forego screening, when the patient first inquired, may have been a sound decision based on the physician's beliefs that the risks of screening outweighed the benefits. The scientific evidence that questions the accuracy of the PSA test and effectiveness of early detection could be cited to support the physician's defense that failing to order a PSA test was not negligent care.

In a malpractice action, however, the final determination regarding the applicable standard of care and whether it was breached will be for the judge or jury as finder of fact. It will be members of the non-medical community that are presented with the controversial and conflicting scientific evidence surrounding the screening issue, as well as the testimony of the patient, or his survivors. The decision maker will be informed that a 50-year-old healthy executive was sufficiently concerned about his strong family history of prostate cancer to seek yearly urological evaluations and inquire about screening. It will be explained that a relatively inexpensive blood test, which has been demonstrated to detect cancer at an early stage, was delayed for a year, and when finally administered revealed evidence of prostate cancer. PSA testing and screening guidelines are so recent that it is impossible to predict with certainty how most courts will ultimately view this scenario.

AVOIDING OR REDUCING LIABILITY

The Physician Insurers Association of America (PIAA), an organization of physician-owned or directed professional liability insurance companies, collects statistical data related to medical malpractice claims. In an analysis of claims involving allegations of the failure to diagnose prostate cancer, PIAA

identified the three medical specialties most often involved in a claim. Of 162 study cases, urologists were named in 65, or approximately 40 percent of cases. General and family practice physicians were named in 42, or approximately 26 percent of cases, and internists were among the named defendants in 36 or 22 percent of cases.[9] (TABLE 1)

PIAA STUDY: DEFENDANTS
n=162

Defendant	Number of Claims	Percentage
Urologists	65	40.1%
General/Family Practitioners	42	25.9%
Internists	36	22.2%

TABLE 1

The PIAA data reflect the respective levels of involvement of the primary physicians as well as urologists in the diagnosis of prostate cancer. In a managed care environment, where an emphasis is placed on limiting sophisticated diagnostic studies and reducing specialty referrals, the primary physician's scope of care has arguably broadened. With this new focus, the need for definitive guidelines in areas such as prostate cancer screening becomes more important.

Randomized, controlled trials are now underway that hopefully will assess the influence of prostate cancer screening on cancer related mortality. Unfortunately, the possibility of definitive evidence on whether such urologic screening and treatment improve health will be unavailable until the turn of the century. Until better data become available, the practitioner is faced with uncertainties and a lack of consensus among advisory groups that provide guidelines. This lack of consensus generates confusion throughout the entire medical community.

Because a number of prominent public figures have "fought the prostate cancer fight," screening, particularly PSA screening, has received wide publicity. Patients who have been influenced by the heavy media coverage often ask their health care provider to perform the test. Although no consensus regarding screening exists, the medical literature suggests measures the practitioner can follow to best deal with a request for screening, and to reduce the potential for liability.

INFORMED CONSENT

The doctrine of informed consent imposes a legal duty upon the physician to provide a patient with sufficient information about the potential side effects of a recommended treatment, in order to allow the patient to make an informed, intelligent choice to either accept or reject treatment or diagnosis. Since the data are unclear, and since patients face potentially serious consequences to health and survival either by accepting or declining the PSA test, obtaining informed consent for PSA screening is especially important.

The first step in obtaining informed consent is educating or counseling the patient, in an unbiased manner, about the benefits and harm that can result from testing and treatment. The uncertainties surrounding prostate cancer screening and treatment should be addressed as well. Following a discussion of potential risks and benefits, the patient's preferences need to be assessed. The patient should consider the procedures that would necessarily follow an abnormal screening result and whether he would want to be treated if cancer were diagnosed.[10]

Through the process of informed consent, the physician and patient establish a relationship based on open communication, patient autonomy and shared decision making. With good rapport between the

patient and the physician, a lawsuit is less likely.[11] Once the patient becomes actively involved in the decision process, he becomes a partner in the relationship and is less likely to have a dispute if complications occur. While there is no arguing with the above principle, in a busy practice the amount of time that can be allowed to completely discuss all aspects of screening is limited.

DOCUMENTATION

The necessity to document in the medical record that a counseling session was held in which the patient was informed of the material risks, benefits, alternatives and uncertainties surrounding screening cannot be overly stressed. Failure to document informed consent gives rise to the presumption that such consent, or the counseling that precedes it, was never given. The patient's chart is viewed as the most reliable indicator of what did or did not happen. The good chart defends itself and those who prepare it. It will enhance better patient care and is the cornerstone of a malpractice prevention program.[12]

COMMUNICATING RESULTS

Medical malpractice claims based on an alleged failure to diagnose occasionally stem from a failure to communicate the results of a diagnostic study. Whether it is a system error, where an abnormal result is not properly forwarded to the appropriate person, or a human error, such as forgetting to notify a patient of the need for further evaluation, the failure to communicate can be a costly and sometimes lethal mistake.

Systems can be altered to decrease the potential for errors. For example, clinical laboratories have administratively developed "panic" values to insure that significantly atypical lab results are handled in a non-routine fashion. Such atypical results are directly and urgently communicated to the requesting physician.[13]

Human errors can be reduced through the use of checklists or protocols designed to reduce one's reliance on memory to communicate results.[14] A risk management protocol which ensures that patients will be notified of all laboratory results, particularly abnormal PSA results, minimizes such error, and fosters open communication between the provider and patient. Counseling the patient to follow-up on their own, if they do not receive their results within a specified time period, provides a safety net if the provider is unable to reach the patient and keeps the patient actively involved in their care.

The practitioner who orders a diagnostic study acquires a legal duty to pursue the results as well as to communicate the results to the patient in a timely fashion. Completed communication is not only a fundamental tenet of clinical risk management, it is also the foundation on which quality care is based.

CONCLUSION

Until there is reliable scientific evidence against screening, a practitioner must decide to screen or to document in detail why he or she did not perform a DRE and PSA. It may be more expedient in many instances to simply order the test than to counsel the patient in detail and carefully document the reason for the decision whether or not to test. Nonetheless, the better practice is to exercise good judgment, engage in full patient communication, and carefully advise the patient on the implications of such tests. There are diverse recommendations and factors to be considered, but on balance, it is usually prudent to perform a DRE and PSA in patients falling within the recommended guidelines.

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ANSWERS TO CME QUESTIONS

1. E	**6. D**	**11. D**	**16. A**
2. B	**7. B**	**12. B**	**17. A**
3. A	**8. D**	**13. A**	**18. B**
4. B	**9. B**	**14. A**	**19. A**
5. A	**10. A**	**15. E**	**20. B**